

**THE HIPAA PRIVACY RULE  
AND  
THE NATIONAL HOSPITAL  
CARE SURVEY**

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## **I. Overview**

Data collected for the National Hospital Care Survey (NHCS) is confidential and strictly protected. This document reviews the authorizing legislation for NHCS, describes the stringent confidentiality provisions of the National Center for Health Statistics and outlines the applicable options that allow hospitals to participate in NHCS under HIPAA. As described in this document, NHCS participation is in accordance with the spirit and the letter of the HIPAA legislation.

## **II. Legal Authority for NHCS**

The central issue of the Privacy Rule is protection of patient health information. Thus, a review of the National Center for Health Statistics' confidentiality and legal authority is provided below.

The authorizing legislation for the NHCS is Section 306(b) of the Public Health Service Act (42 USC 242k) which addressed the essential importance of collecting information about the Nation's health. Section 308(d) of this act establishes a confidentiality requirement, which makes it unlawful to use identifiable information for any purpose other than that for which it was supplied or to publish or release such information in any other form when the establishment or person is identifiable, without the consent of the participant.

The National Center for Health Statistics and its agents (contractors and subcontractors) are, and have been, legally bound by these confidentiality restrictions. With the enactment and implementation of the Federal privacy regulations, hospitals now are subject to restrictions and limitations on how the personal health information they maintain is used and disclosed, including information provided to the National Center for Health Statistics.

## **III. Requirements of the HIPAA Privacy Rule**

HIPAA was passed in 1996 but the Privacy Rule of HIPAA went into effect April 14, 2003. The privacy provisions of HIPAA grant the Department of Health and Human Services authority to regulate the uses and disclosures of protected health information maintained by "covered entities", such as hospitals.

Protected health information (PHI) is information created or received by the hospital that

- relates to an individual's physical or mental health, treatment, or payment, and that
- identifies an individual or gives reasonable basis to believe that the information can be used to identify the individual.

The privacy standards of HIPAA are meant to protect patients from unnecessary, inappropriate and/or inadvertent use or disclosure of their personal health information. HIPAA is not intended to interfere with patients' access to health care or affect the quality of the health care received. HIPAA limitations and controls do not apply to uses and disclosures of information for treatment or payment purposes, or for routine health care operations. Therefore, "incidental" uses or disclosures are exempt from the privacy provisions of HIPAA. An incidental use or disclosure refers to any secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and occurs as a by-product of another permissible or required use or disclosure. (For example, a doctor speaking with a patient in a shared hospital room may result in an incidental disclosure of health information.)

#### IV. Extra Safeguards and Protections Required by HIPAA

HIPAA Privacy Notice: The Privacy Rule requires that hospitals notify patients about their privacy rights and how their health and medical information may be used. The HIPAA Privacy Notice must inform patients of uses and disclosures which the hospital may make without their individual authorization, and state that other uses and disclosures will be made only with their individual authorization.

Individual Authorization: The Privacy Rule also requires that, in general, patients should explicitly authorize the use and disclosure of their protected health information. But there are circumstances in which individual authorization may be waived or is not required. As described in Section V, Compliance Options Permitted Under HIPAA, hospitals participating in the NHCS can disclose information without individual authorization and still maintain compliance with the law.

Minimum Necessary Standard: Uses and disclosures of information that are not related to treatment, payment, or health care operations, and that are not incidental are subject to criteria called the “minimum necessary standard”. That is, HIPAA requires hospitals to implement policies and procedures that limit:

- **how much** protected health information is disclosed for certain purposes;
- **who** within the entity has access to protected health information, and
- **under what conditions** access is permitted based on job responsibilities and the nature of the business.

Incidental uses and disclosures of protected health information are in general permitted when the provider has in place safeguards, policies, and procedures to protect an individual’s privacy. HIPAA permits hospitals to rely on the judgment of a public health agency or a researcher’s Institutional Review Board (IRB) that the information requested is the minimum necessary for their particular purposes.

Accounting Documentation: In some circumstances HIPAA requires hospitals to keep a record, an “accounting”, of all disclosures of patients’ protected health information. Details of the accounting and how it is handled for the NHCS are discussed in Section V.

#### V. Relevant Compliance Options Permitted Under HIPAA

The NHCS is conducted under the regulations permitting hospitals to disclose PHI for *public health purposes* and for *research purposes* when the research has been approved by an Institutional Review Board.

**For the NHCS**, the HIPAA Privacy Rule permits disclosure of protected health information without patient authorization for 1) public health purposes, and 2) research that has been approved by an IRB.

##### **Use and Disclosure for Public Health Purposes:**

The Privacy Rule permits hospitals to disclose protected health information without individual authorization to public health authorities who are legally authorized to receive or collect data for the purpose of reporting disease or injury statistics and vital events, as well as conducting public health surveillance, investigations, or interventions.

CDC is a public health agency and is governed by Public Health Service Act which describes the public health activities mandated by that law for the National Center for Health Statistics. If a hospital agrees to this approach to participate in the NHCS, then it is not

necessary to obtain individual patient authorization for release of their protected health information.

Further, the Privacy Rule permits the hospital to rely on the judgment of the public health agency (i.e., CDC) as to the minimum necessary information needed to achieve the public health purpose for which the data are requested. The hospital thus meets the minimum necessary standard required by the Rule to protect patients' health information.

Under this option, hospitals must comply with the notification and accounting requirements of the Rule. To satisfy the notification requirement, hospitals are required to state in their Privacy Notice that patients' health information may be used for public health purposes.

#### **Use and Disclosure for Research Purposes:**

The Privacy Rule also recognizes the need for access to medical information to conduct research. It is with this understanding that hospitals can legitimately participate in the NHCS under the research clause of the Privacy Rule. Hospitals are permitted to disclose protected health information for research when the research has been approved by an Institutional Review Board (IRB) or Privacy Board and such approval includes a Waiver of Patient Authorization for Release of Patient Medical Record Data by Health Care Providers. The National Center for Health Statistics Research Ethic Review Board (ERB) has approved a Waiver of Patient Authorization for Release of Patient Medical Record Data by Health Care Providers for the NHCS. Additionally, the National Center for Health Statistics' ERB approved a Waiver of the Requirements to Obtain Informed Consent from the Patients and a Waiver of the Requirements to Obtain Informed Consent from the Physicians. The ERB approval letter for the NHCS is available on the NHCS website (<http://www.cdc.gov/nchs/nhcs/participant.htm>).

Hospitals are explicitly permitted by the HIPAA Privacy Rule to exercise reasonable reliance on the researcher's documentation of the IRB (or Privacy Board) Waiver of Authorization that the information requested is the minimum necessary for the research purposes.

In the event that a patient requests information about disclosures of their protected health information, hospitals are required to keep Accounting Documentation for 6 years. The National Center for Health Statistics has developed an accounting document for NHCS hospitals ("NHCS Documentation Notice for HIPAA Accounting – Individual Form," Exhibit A). This documentation allows hospitals to respond to requests by patients for disclosures made of their protected health information.

A separate accounting document (Exhibit A-Hospital Form) will be provided to hospitals to simplify their record-keeping and for their convenience in complying with this requirement.

#### **VI. What Does This All Mean for Participation in NHCS?**

The documents that the National Center for Health Statistics has developed for hospitals to participate in the NHCS and comply with HIPAA have been reviewed by CDC's Office of General Counsel. The Center has developed these documents and forms to assist them in complying with the law while maintaining their participation in the NHCS, but of course hospitals are not required to accept what the Center has developed.

Additional information about the Privacy Rule of HIPAA is available from various Websites listed in Exhibit B.

## VII. Glossary

Accounting of Disclosures: Under HIPAA hospitals are required to be able to tell patients how their protected health information has been disclosed. The mechanism for this is an Accounting Document. The accounting document in Exhibit A meets the HIPAA requirement. It should be kept by the hospital for 6 years.

Business Associate: A person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity (hospital) in the conduct of their health care activities. The types of functions that may make a person or entity a business associate include payment or health care operations activities, such as claims processing and administration; data analysis, processing or administration; utilization review; billing; benefits management; quality assurance, etc. In most cases, the Privacy Rule requires a covered entity to enter into a written contract with its business associates.

Covered Entity: For the NHCS, this means "hospital," but in the law it includes other health care providers such as doctors' offices, emergency rooms, outpatient departments, nursing homes, dentists, etc. It also covers health care plans and health care clearinghouses.

Data Use Agreement: Terms agreed to by a researcher for the purpose of stipulating how the researcher may use the Limited Data Set. The Data Use Agreement option does not apply to NHCS.

De-Identified Health Information: Health information that does not identify an individual and for which no reasonable basis exists to believe that it could be used to identify an individual.

Disclosure: The release, transfer, provision of access to, or divulging in any other manner, information to any entity outside the entity (hospital for the NHCS) holding the information.

Incidental Use/Disclosure: A disclosure that cannot reasonably be prevented, is limited in nature, and occurs as a by-product of health care activities, e.g., a doctor speaking with a patient about his/her condition in a shared hospital room.

Individual Patient Authorization: A document signed by a patient that gives hospitals (or other health care providers) permission to use protected health information for specified purposes (e.g., research) which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.

Individually Identifiable Health Information: See Protected Health Information (PHI) below.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of individuals who participate in research activities conducted by the institution with which the IRB is affiliated. A major responsibility of an IRB is to determine whether provisions to protect the privacy of research participants and to maintain the confidentiality of the data are adequate. An IRB can be used to review and approve a researcher's request to waive or alter the Privacy Rule's requirements for an Individual Patient Authorization.

Limited Data Set: A data set containing protected health information, but excluding direct identifiers, such as

- Names
- Postal address information other than town or city, state, and ZIP Code
- Telephone numbers
- Electronic mail (email) addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers

Minimum Necessary Standard: Requires covered entities to implement policies and procedures that limit

- how much protected health information is used, disclosed, and requested for certain purposes;
- who within the entity has access to protected health information, and
- under what conditions access is permitted based on job responsibilities and the nature of the business.

Privacy Notice: A document that meets the HIPAA requirement to notify patients of uses and disclosures that may be made of their protected health information by a covered entity.

Protected Health Information (PHI): Information created or received by a health care provider (hospital in this case) that relates to an individual's physical or mental health, treatment, or payment (past, present, or future), and that identifies an individual or gives reasonable basis to believe that the information can be used to identify the individual. Also known as Individually Identifiable Health Information.

Public Health Authority: An agency or authority that is responsible for public health matters as part of its official mandate. Examples of public health authorities include state and local health departments, CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

Waiver of Authorization of Patient Consent: As stated above in "Individual Authorization" patients can authorize hospitals to allow their data to be used for research. However, in many cases this authorization is not possible or practical. A Waiver of Authorization is permission obtained from an official body known as an Institutional Review Board (IRB) or a Privacy Board that states that the IRB or Privacy Board has waived or altered the HIPAA requirement that an individual must authorize a covered entity (hospital) to use or disclose the individual's protected health information for research purposes.

Waiver of the Requirements to Obtain Informed Consent from the Patients: Documentation that a covered entity obtains from a researcher, an IRB, or a Privacy Board that states that the IRB or PB has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

Waiver of the Requirements to Obtain Informed Consent from the Physicians: Documentation that a covered entity obtains from a researcher, an IRB, or a Privacy Board that states that the IRB or PB has waived or altered the Privacy Rule's requirement that a physician must authorize a covered entity to use or disclose the physician's PHI for research purposes.

## **Exhibit A: NHCS Documentation Notice for HIPAA Accounting – Individual Form**

Information contained in this document can be used to comply with the Privacy Rule requirements as mandated by the Health Insurance Portability and Accountability Act (HIPAA) to account for disclosures of protected health information.

Disclosure date: \_\_\_\_\_

Name and address of recipient:

Westat as data collection agent for the  
Centers for Disease Control and Prevention  
National Center for Health Statistics  
Division of Health Care Statistics  
3311 Toledo Road  
Hyattsville, MD 20782

Purpose:

CDC's National Center for Health Statistics (NCHS) is charged with measuring the nature and amount of health services provided in the United States. As part of this mission, NCHS conducts the National Hospital Care Survey (NHCS). The inpatient component of the NHCS collects information on characteristics of inpatients discharged from nonfederal non-institutional hospitals in the U.S. The resulting published statistics will help the medical profession plan for more effective health services, improve medical education, and assist the public health community in understanding the epidemiology of diseases and health conditions that affect Americans.

Description:

This document has been placed in the medical file as an indicator that information was used for the NHCS on the above date. Information was pulled from UB-04 administrative claims forms and may have included various inpatient characteristics (e.g., demographics, diagnosis, and procedures). This particular hospital was randomly selected to be included in the NHCS. Directly identifiable information collected as part of this discharge is maintained separately from detailed information about the hospital stay. The information collected will be used to generate nationally representative data on utilization of hospital care and general purpose health care statistics.

## **EXHIBIT A: NHCS Documentation Notice for HIPAA Accounting – Hospital Form**

Information contained in this document can be used to comply with the Privacy Rule requirements as mandated by the Health Insurance Portability and Accountability Act (HIPAA) to account for disclosures of protected health information.

This hospital participated in the National Hospital Care Survey (described below). Information was disclosed for UB-04 administrative claims for all patients; therefore, the hospital is not required to account for disclosures of information about any particular individual. Protected health information of any particular individual may or may not have been disclosed for this research activity.

Disclosure date: \_\_\_\_\_

**Name and address of recipient:**

Westat as data collection agent for the  
Centers for Disease Control and Prevention  
National Center for Health Statistics  
Division of Health Care Statistics  
3311 Toledo Road  
Hyattsville, MD 20782

**Purpose:**

CDC's National Center for Health Statistics (NCHS) is charged with measuring the amount and nature of health services provided in the United States. As part of this mission, NCHS is conducting the National Hospital Care Survey (NHCS). The inpatient component of the NHCS collects information about the characteristics of inpatients discharged from nonfederal non-institutional hospitals and the care provided while they are inpatients. The resulting published statistics will describe the structure of the current health care delivery system and the current distribution of the population. This information will be used to help policy makers, health care researchers, and others in planning for more effective health services, improving medical education, and assisting the public health community in understanding the epidemiology of diseases and health conditions that affect Americans.

**Description:**

This document provides documentation that information from discharges for this hospital was used for the NHCS. Information was pulled from UB-04 administrative claims forms and may have included various inpatient characteristics (e.g., demographic information, diagnosis, and procedures). This particular hospital was randomly selected to be included in the NHCS. Directly identifiable information collected as part of this survey is maintained separately from detailed information about the hospital stay. The information collected will be used to generate nationally representative data on utilization of hospital care and general purpose health care statistics.

**Exhibit B: Websites Which Provide Information and Technical Assistance  
Regarding the HIPAA Privacy Rule**

**Federal Government Resources**

**DHHS Office for Civil Rights --- HIPAA guidelines**

<http://www.hhs.gov/ocr/hipaa>

**CDC --- Privacy Rule guidelines**

<http://www.cdc.gov/privacyrule>

**Centers for Medicare and Medicaid Services**

<http://www.cms.gov/hipaageninfo/>

<http://www.cms.gov/hipaageninfo/downloads/hipaalaw.pdf>

**Health Resources and Services Administration --- HIPAA**

<http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/PrivacyandSecurity/privacyinformation.html>

**Indian Health Service --- HIPAA**

<http://www.ihs.gov/AdminMngrResources/HIPAA/index.cfm>

**National Institutes of Health**

<http://privacyruleandresearch.nih.gov>

**Substance Abuse and Mental Health Services Administration --- HIPAA**

<http://www.samhsa.gov/healthprivacy/>